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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,874	10/15/2001	Barry J. Marshall	BAL-106(17349)	3775

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EXAMINER

LEARY, LOUISE N

ART UNIT PAPER NUMBER

1654

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,874

Applicant(s)

MARSHALL ET AL.

Examiner

Louise N. Leary

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-19 is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-9 is/are rejected.
- 7) ☒ Claim(s) 5-6,9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,6-8.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. Claims 1-19 are pending in this application.
2. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-19 are indefinite because the metes and bounds intended for the phrase "well suited" have not been defined in the claims. Alternatively, the phrase "well suited" is ambiguous and does not distinctly describe the material claimed. It is suggested that the phrase "well suited" be deleted for clarity of the claims and to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "the bactericide" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, and 7 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hayakawa et al (US 6,294,151).

Hayakawa et al disclose a tablet containing urea and an inorganic compound containing silica. See the Abstract and column 1, lines 36-47 and lines 61-63. Hayakawa et al disclose using the tablet containing urea for diagnosing stomach infections with urease generating *Helicobacter pylori* bacteria. Note column 1, lines 1-25. Regarding the inorganic compound in the tablet, Hayakawa et al disclose silicic acid anhydride, silicic acid and silicate as examples of the inorganic compounds containing silica. Note column 1, lines 61-68 and column 2, lines 1-16. With respect to the use of an indicator that changes color, Hayakawa et al disclose examples of coloring agents additionally included in the tablet. See column 3, lines 12-14. In regards to the powder limitation in the instant claims, Hayakawa et al disclose "together with the compounds shown in Table 1, urea was ground and mixed in a mortar" and describes a urea and light anhydride silicic acid powder mixture. See column 4, lines 35-57 and column 9, lines 120-28. Further, with respect to the particle size; powder and anti-caking agent descriptions in the instant claims, Hayakawa et al disclose anti-sticking tablet formulations and disclose that "...urea and light anhydride silicic acid were mixed together, and the resulting mixture was ground by a grinder... to a final average particle diameter to 100 um or less". See column 9, lines 30-38 and the entire document. Thus, Hayakawa et al disclose the invention claimed except for using the phrase "anti-caking agent".

However, Hayakawa et al address the "anti-caking agent" limitation claimed in the disclosure of anti-sticking tablet formulations comprising urea and inorganic compounds that inherently perform the function of the instantly claimed "anti-caking agent". The Hayakawa et al reference discloses all the limitations claimed which anticipates or renders obvious the present invention.

Therefore, the burden of proof is on applicants to show patentably distinct differences between the urea tablet compositions in the Hayakawa et al disclosure and the urea material compositions claimed in the present invention.

4. Claims 5-6 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
5. Claims 10-19 are allowable over the prior art of record.


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 9:30 to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

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LOUISE N. LEARY
PRIMARY EXAMINER

February 21, 2003